VALIDATION AND COMPLETION OF MINOR AMENDMENTS TO ADULT & PAEDIATRIC REGIMENS IN ARIA

Objective

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure to be followed when applying minor amendments or updates to chemotherapy or other SACT regimens (referred to as chemotherapy regimens) and symptom management plans (referred to as support regimens) in the ARIA electronic prescribing system (referred to as ARIA). All chemotherapy and support regimens will be built in the ARIA Planner app, then tested and validated in the Planner and Manager apps.

Scope

This SOP ONLY applies to the validation of changes to adult and paediatric chemotherapy and support regimens, where such changes fall in to the stated sections of **KMCCEP023 Building & Validating Adult & Paediatric Chemotherapy Regimens and Symptom Management (Support) Plans** as listed in the Build SOP ref column of the checklist. All other changes should be validated using the full validation process as outlined on the ARIA regimen validation SOP. This SOP does not address minor amendments to clinical trial regimens.

Responsibilities

- The ARIA system administrator is responsible for allocating and overseeing the building and validation of all chemotherapy and support regimens in ARIA as stated in **KMCCEP001 Aria Regimen Building and Validation Process Following Protocol Approval**. The validation of chemotherapy regimens must always be carried out by someone other than the person who built the regimen on ARIA Planner.
- The following checklist should be completed by the authorised technician or pharmacist who makes the changes to the regimen on ARIA and the changes validated by a second authorised pharmacist.
- The completion checklist should be completed by the technician or pharmacist who makes the regimen live.

Method

- Reference should be made to the latest **KMCCEP023 Building & Validating Adult & paediatric Chemotherapy Regimens and Symptom Management (Support) Plans**.
- Requests for amendments should be made by the relevant NOG or following an update to a K&M SACT protocol then submitted to the system administrator. In exceptional circumstances, there may be instances where a regimen is copied as a support regimen and this SOP should also be used to document that process.
- The amendment should be checked both in Planner and Manager, as outlined below.
- When testing the amendments in Manager, the test patient from the original validation should be used. The regimen can be discontinued and re-prescribed but orders from the previous regimen should never be amended, deleted or errored.
- When updating an approved regimen, if Amendments Mandatory is ticked on the current Approved regimen, the regimen **MUST** be copied then re-built to remove this tick and **NOT** amended. If the changes to the copied regimen meet the criteria of a minor amendment then this SOP may be followed.

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Regimen name		Regimen version		Regimen Date*	Regimen Date
Copied regimen name (if applicable)		Regimen version		Regimen Date*	Regimen Date
Test patient name from full validation		CCF number and/or KMCC protocol version		Build SOP version	

Build SOP ref	DESCRIPTION OF CHANGE (state details of change made in the box)	Tick if changed
PLANNER CHECKS		
DEFINITION (MODIFY PLAN)		
1.1.1	Amendment to the plan name (only for copied regimens)	✘
1.1.3	Amendment to the display name	✘
1.1.4	**Plan Type** Change when copying a regimen to create a support regimen	✘
1.1.10	'Amendments Mandatory' box must NOT be ticked Check and action on ALL regimens	✘
1.2.3	**Change to Classification type box** If copying a regimen to make a support regimen, remove disease site and cancer categories and add in appropriate 'Problem'	✘
1.4	Change to Authorized Users	✘
MODIFY PHASE		
2.14	**Description Box:** If text is present it should be deleted	✘
2.3	**Phase Name:** Complete only for support regimens	✘
2.6	Change to modality	✘
2.10	**Change number of cycles** Regimens with cyclical agents only. Amend / check under modify phase.	✘
	PRINT EVENT LIST IF A CHANGE HAS BEEN MADE TO THE NUMBER OF CYCLES	
ADD/VIEW/MODIFY AGENTS		
	Delete a drug Non-SACT drugs can be deleted from a regimen. Scheduling must be deleted first, before the drug can be deleted	✘
3.1	Add drugs To add non-SACT drugs to a regimen. If a SACT drug needs to be added then a full regimen validation will be required	✘
4.1.1 – 4.1.15	Changes to the Details tab (except diluent details) Dose changes are permitted on all non-SACT drugs. Changes to SACT doses require a full validation.	✘

4.1.16–4.1.18	**Changes to the diluent details within Details Tab** Including diluent, infusion mode, volume, duration and rate.	✘
4.2	**Change to the free text within the Admin tab.** Ensure no additional changes to the Details tab or Schedule Events are required as a result of this change.	✘
5	**Change to the scheduling** Scheduling changes are permitted on all non-SACT drugs and schedule changes from 'days' to 'doses' is permitted on ALL SACT and non-SACT drugs. Any other changes to SACT drug scheduling require a full validation	✘
PLAN SUMMARY		
9	**Change to the free text within the Plan Summary** Ensure no additional changes to the Details tab or Schedule Events are required as a result of this change.	✘

MANAGER CHECKS (Validating pharmacist only)

LOG INTO ARIA MANAGER AT "TEST LOCATION - OUTPATIENT" FOR ADULT REGIMENS OR TWH Paed – TEST LOCATION FOR PAEDIATRIC REGIMENS AND CREATE OR SELECT THE APPROPRIATE TEST PATIENT. OPEN THE MEDICATIONS WINDOW BY CLICKING ON THE "Rx" ICON ON THE TOOLBAR. SELECT THE RELEVANT CANCER DISEASE SITE FOR THE REGIMEN THAT YOU WILL BE TESTING. HIGHLIGHT THEN ORDER YOUR REGIMEN FOR THE TEST PATIENT

- Are all the agents still in the correct administration sequence as shown in Planner? For regimens with more than one scheduled treatment day, all 'Internal' agents are listed first, followed by all 'Pickup - Internal' agents.
- Are all the agents correct in terms of routes of administration, diluents, infusion volumes and durations?
- For each agent click on the Administration Instructions box and check that the administration instructions are correct

TAKE A SCREENSHOT OF THE CHANGE

Errors detected requiring correction (list test numbers) and errors found that were not covered in Checklist procedure:

Builder (Print Name)		**Signed**	
Designation		Date	
I CONFIRM THAT THE REGIMEN HAS PASSED ALL REQUIRED TESTS			
Validated by (Print Name)		**Signed**	
Designation		Date	

COMPLETION OF MINOR VALIDATIONS						
DOCUMENTATION CHECKS Signed documents received						✓ when completed
Screenshots from pharmacist						
Prescription print-out (not always needed for minor amendment)						
Correct version of SOPs used						
All related CCFs returned and completed (check with system administrator if unsure)			**CCF**			
CONFIGURE ACCESS						
Check the regimen in the test location in Manager to ensure scheduling is still present. If not, refer back to validating pharmacist						
Check that the protocol is in the final folder and that there are no versions in draft in the document management system						
Check that the correct version (the approved final draft), as stated on the regimen work plan has been used for the build and validation						
Update the references in Plan Summary with the final version number	Version from		Version to			
Update authorised users with the lead EP pharmacist from each Trust, the KMCC pharmacists, the system administrator and the Varian user						
For network approved regimens: Grant access to all locations as appropriate to the regimen type i.e. all non-test adult locations for an adult regimen and all non-test paediatric locations for a paediatric regimen. **For non-network approved regimens:** ONLY grant access to locations within each Trust who have approved its use and as appropriate to the regimen type, and exclude any prescribers prohibited from using the regimen. The lead e-prescribing pharmacist will be authorised to allow the use of a non-trials regimen within their Trust. In all cases, do not grant access at Radiation Scheduling location.						
MAKE REGIMEN LIVE						
Approve Plan - Click 'Analyse' and then 'Approve for use'						
If amending or superseding a regimen, deactivate the previous regimen(s)/version(s)			Deactivated version:			
In Manager, using XXAccess, Test for adult regimens and XXPaed, Test for paediatric regimens, check the regimen is available in one of the locations selected, as appropriate for the regimen type						
Check that the scheduling is still present for the regimen. If not, refer back to validating pharmacist						
CREATE AND FILE BACK-UP TEMPLATE						
Non-MTW users ensure that the default printer is set to 'docu-printer' via File – Printer setup before proceeding **Run the report:** Manager - Reports – 'Prescriptions – Daily doses – Template – QA CUSTOM' - Enter *Plan Name* - 'Preview' then **Save the report:** For MTW users: Click the 'Export' icon. For non-MTW users: Click the 'Print' icon						
Upload the template to the regimen library in the document management system.						
Inform the system administrator who will inform relevant users. In their absence, inform the relevant pharmacy leads						
Print name			**Signed**			
Designation			Date			
ONCE COMPLETED, SAVE THIS FORM WITH THE VALIDATION DOCUMENTS IN THE DOCUMENT MANAGEMENT SYSTEM						

* Regimen date should be the date the regimen was first created. This can be found in the Modify Plan window – Definition tab. Click on the Audit symbol and enter the created date.

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